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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,180	04/07/2004	Peter M. Bonutti	2515 CIP DIV 2 CON B CON	7364
7590 Kimberly V. Perry U.S. Surgical A division of Tyco Healthcare Group LP 150 Glover Avenue Norwalk, CT 06856			EXAMINER SONNETT, KATHLEEN C	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 08/13/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/820,180	Applicant(s) BONUTTI, PETER M.	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17, 19-21, 23-25 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17, 19-21, 23-25 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 12-16, 19, 20, 24, 25, 32, and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Saudagar (US 4,555,242). Saudagar discloses a surgical device capable of providing a working passage through tissue, the device comprising an elongate tubular member (12) having proximal and distal openings defining a bore (14) therethrough, the bore forming the working passage for an operating tool, and a plurality of wall segments (30) disposed on the tubular member, each wall segment having an inflated and uninflated state, wherein the plurality of wall segments includes at least two wall segments (two adjacent segments 30) in abutting relationship when in the uninflated state (figs. 1,2).

3. Regarding claim 13, the bore is capable of receiving an endoscopic instrument. Since the endoscopic instrument itself is not claimed, the device must only be capable of receiving such an instrument. It is further noted that any endoscopic instrument can be chosen including one that is sized to pass through the bore in tubular member (12).

4. Regarding claim 14, see fig. 1.

5. Regarding claim 15, the surface of each wall segment is being considered “substantially flush” with an exterior surface of the tubular member when the wall segment is in the uninflated state (fig. 2, dotted representation of inflatable portion of areas 30).

6. Regarding claim 16, each wall segment has an outside diameter greater than an outside diameter of the tubular member when the wall segment is in the inflated state (see fig. 2).

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7. Regarding claim 19, Saudagar discloses a method of positioning a surgical access device through tissue of a patient, the method comprising the steps of inserting the surgical access device through tissue (col. 4 ll. 32-37), the device comprising an elongate tubular member with a bore therethrough and a plurality of inflatable wall segments including at least two wall segments in abutting relationship when in the uninflated state, introducing a fluid under pressure to a first wall segment causing it to go from its uninflated state to its inflated state (col. 4 ll. 52-54), and positioning the access device such that at least a portion of the first wall segment is in contact with tissue. As shown in fig. 2, the device has been introduced into tissue and the first wall segment is in contact with tissue.

8. Regarding claim 20, as discussed above, the bore is capable of accommodating an endoscopic instrument.

9. Regarding claims 24 and 25, the tubular member of Saudagar is described as flexible but can be considered to have some rigidity since it does not collapse in on itself (see also 35 USC 112 rejections above).

10. Regarding claims 32 and 33, the at least two wall segments are adapted to maintain their abutting relationship during inflation and when in the inflated state.

11. **Claims 12, 13, 16, 17, 19-21, 24, 25, 34-36** are rejected under 35 U.S.C. 102(b) as being anticipated by Sogawa et al. (US 5,308,323). Sogawa discloses a surgical device capable of providing a working passage through tissue, the device comprising an elongate tubular member (1) having proximal and distal openings defining a bore (7) therethrough, the bore forming the working passage for an operating tool, and a plurality of wall segments (2 divided by radial walls 3) disposed on the tubular member, each wall segment having an inflated and uninflated state, wherein the plurality of wall segments includes at least two wall segments (two

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adjacent sections 2 corresponding to adjacent compartments 4) in abutting relationship when in the uninflated state (figs. 1-4).

12. Regarding claim 13, the bore is capable of receiving an endoscopic instrument.

13. Regarding claim 16, each wall segment, when inflated, has a diameter greater than the diameter of the tubular member.

14. Regarding claim 17, the sections are selectively inflatable such that, when at least two of the plurality of wall segments are in the inflated state, there is a gap between them. That is to say, when two of the three segments shown in fig. 2 are inflated, there is a gap formed where the third, uninflated segment remains.

15. Regarding claim 19, Sogawa discloses a method of positioning a surgical access device through tissue of a patient, the method comprising the steps of inserting the surgical access device through tissue (fig. 3; inserted through vessel "A"), the device comprising an elongate tubular member with a bore therethrough and a plurality of inflatable wall segments including at least two wall segments in abutting relationship when in the uninflated state, introducing a fluid under pressure to a first wall segment causing it to go from its uninflated state to its inflated state (col. 2 ll. 56-64), and positioning the access device such that at least a portion of the first wall segment is in contact with tissue.

16. Regarding claim 20, the bore is capable of receiving an endoscopic instrument.

17. Regarding claim 21, Sogawa discloses inflating a second wall segment (col. 3 ll. 7-10). Inflating multiple compartments at the same time such as two of the compartments results in a gap between the first and second wall segment where the third, uninflated segment remains.

18. Regarding claims 24 and 25, the tubular member of Sogawa can be considered to have some rigidity since it does not collapse in on itself (see also 35 USC 112 rejections above) during use and is able to advance through the vessel.

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19. Regarding claims 34-36, Sogawa discloses an elongate tubular member with a passage configured to removably receive an operating tool and a plurality of selectively inflatable wall segments disposed along the tubular member each configured to engage tissue in a substantially sealed relation upon the inflation thereof such that tissue may be sealed at one or more locations along the tubular member. There are at least two wall segments in abutting contact as discussed above. The segments can engage tissue in a sealed relation if the opening in the tissue in which they are inserted is small enough to contact the device when a segment is inflated.

20. Regarding claims 35 and 36, the two wall segments are in abutting contact at all times.

21. **Claims 12-16, 19, 20, and 23-25** are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue (US 4,453,545). Inoue discloses a surgical device for providing a workspace passage through tissue, the device comprising an elongate tubular member having proximal and distal openings defining a bore therethrough which forms a working passage for an operating tool, and a plurality of wall segments disposed on the tubular member, each wall segment having an uninflated and inflated state wherein the plurality of wall segments includes at least two wall segments in an abutting relationship when in the uninflated state. Looking at the inflatable cuff (41) in fig. 6, this cuff can be considered to be made up of a plurality of wall segments which are joined together to form the entire cuff. Two segments next to each other are in an abutting relationship.

22. Regarding claim 19, Inoue discloses a method of positioning a surgical access device through tissue of a patient comprising the steps of inserting the surgical access device through tissue (see fig. 7a), the device comprising an elongate tubular member with a bore therethrough and a plurality of inflatable wall segments including at least two wall segments in abutting relationship when in the uninflated state, introducing a fluid under pressure to a first wall

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segment causing it to go from its uninflated state to its inflated state (col. 2 ll. 35-39), and positioning the access device such that at least a portion of the first wall segment is in contact with tissue (fig. 7a). The method includes inserting the device through tissue since the device is inserted through the lumen of the trachea, which comprises tissue.

23. Regarding claims 13 and 20, the bore is capable of receiving an endoscopic instrument.

24. Regarding claim 14, the segments can be considered adjacent circumferential sections of cuff 41.

25. Regarding claims 15 and 16, see fig. 6 and fig. 7a, which show the segments in their inflated and uninflated configurations.

26. Regarding claim 23, Inoue further discloses including a retractor repositionable through the elongate tubular member, the retractor comprising a shaft (51) having proximal and distal openings (inflation fluid enters and leaves passage 55) with a bore (55) therethrough and an expandable member (41') attached at a distal end of the shaft and in fluid communication with the proximal opening of the shaft. This element is being considered a retractor as it is capable of retracting tissue when inflated and pushed against tissue.

27. Regarding claims 24 and 25, the member is being considered rigid as it has enough pushability to be able to be advanced down the trachea.

Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

29. **Claims 34-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Oddo (US 2,849,001) in view of Oddo (US 2,849,002). Oddo '001 discloses a surgical device

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comprising an elongate tubular member (10) defining a passage (11) therethrough that is configured to removably receive an operating tool (such as a guidewire) and a plurality of inflatable wall segments (14, 15; figs. 1-3) disposed along the tubular member, each segment being configured to engage tissue in a substantially sealed relation upon the inflation thereof such that the tissue may be sealed at one or more selected spots along the tubular member, wherein the plurality of wall segments includes at least two wall segments in abutting relationship (see sections 14 and 15; fig. 3).

30. Regarding claims 35 and 36, the at least two wall segments are in an abutting relationship before, during, and after inflation.

31. Oddo '001 fails to disclose that the inflatable wall segments are selectively inflatable as they share a common inflation lumen. However, Oddo '002 teaches that it is old and well known to include separate lumens for two inflatable wall sections on a surgical device similar to the one disclosed by Oddo '001 (see fig. 3; "17","19"). In particular, Oddo '002 teaches that, although a common inflation port can be used to simultaneously inflate both balloons, it is advantageous to have selectively inflatable balloons because such structure allows pressure in each balloon to be individually varied (col. 2 ll. 47-65) thereby increasing control over the device. It would have been obvious to one skilled in the art to have modified the device of Oddo '001 to include a second inflation lumen and port allowing the balloons to be selectively inflatable as taught by Oddo '002 in order to gain the advantage of being able to increase control over inflation of the inflatable wall segments.

Response to Arguments

32. Applicant's arguments filed 5/13/2008 have been fully considered but they are not persuasive. Applicant argues that Saudagar fails to disclose a plurality of wall segments each having an uninflated state and an inflated state, wherein the wall segments include at least two

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wall segments in an abutting relationship. However, as discussed in the rejection, the wall of the inflatable portion (28) can be considered to comprise a plurality of wall segments in abutting contact which have an inflated and uninflated state. There is nothing in the claim that distinguishes the claimed plurality of wall segments from the prior art of Saudagar. The examiner used the corrugations merely to show on the figure what can be considered wall segments that abut one another and have both an inflated and uninflated configuration.

33. Regarding the rejections over Sogawa, it is noted that the examiner used elements (3) and (2) to point out what is being considered wall segments. The wall segments in abutting contact can be considered adjacent portions (2) which abut at (3). Applicant argues that the device of Sogawa is only a single balloon. However, it is noted that a single balloon can be considered to be made of a plurality of inflatable wall segments in abutting contact.

Furthermore, the inflatable portion of Sogawa has individually inflatable wall segments (three areas of (2) as divided by radial wall (3)) because the compartments (4) are individually provided with their own fluid supply.

34. Regarding the rejections over Inoue, a single inflatable element can be considered to include a portion of inflatable wall segments in abutting contact. There is no language in the claims rejected over Inoue that necessitates any sort of space between the wall segments or that they are individually inflatable.

35. Applicant also argues that the tubular body portion of Oddo '001 does not include a passage therethrough. However, the passage of the tubular body portion includes a distal opening (13) and a proximal opening and therefore it is the examiner's position that hole (13) is formed near enough to the distal tip of the device (see figs. 1-3) that the passage within the tubular body portion can be considered to be formed "therethrough". In response to applicant's argument that this channel is not configured to receive an operating tool, a recitation of the

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intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The channel is capable of receiving an operating tool such as a wire.

36. Applicant's arguments regarding the 35 USC 112 1st paragraph and 2nd paragraph rejections of claims 24 and 25 are persuasive and this rejection has been withdrawn. Applicant's amendments have overcome the previously presented 35 USC 112 2nd paragraph rejections of claims 32, 33, 35 and 36.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 8/5/2008

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731